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09/771,045	01/26/2001	Jonathan P. Duvick	1134C	7253

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 01/13/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/771,045	DUVICK ET AL.
	Examiner	Art Unit
	Medina A Ibrahim	1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 04 November 2002.

2a) This action is FINAL.                                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) 9-11 and 20-22 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-8 and 12-19 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)                                    4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                            5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.                            6) Other:

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-8 and 12-19 and SEQ ID NO: 35 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that no separate search is required to search the non-elected groups because all claims are related as product and process of use. This is not found persuasive because the three groups define three independent and distinct inventions for the reasons of record as set forth in the last Office action. In addition, the literature search of the three groups is highly divergent, and searching them together will pose series burden on the Examiner, even if some of the search overlap. Therefore, the restriction requirement is still deemed proper and is made FINAL.

Claims 1-22 are pending.

Claims 1-8 and 12-19 are under examination

Claims 9-11, 20-22 and claims drawn to SEQ ID NO: 37, 39, 41, 43 and 45. are withdrawn from consideration as being drawn to a non-elected invention.

### ***Sequence Listing***

Applicant's CRF and paper sequence listing have been entered.

### ***Information Disclosure Statement***

Initialed and dated copy of the IDS form 1449 of Paper no. 5 is attached to the instant Office action.

### ***Drawings***

No drawings have been filed with this application

***Priority***

The status of parent application nos. 09/352, 168 and 09/352, 159 should be updated.

***Specification***

1. The disclosure is objected to because of the following informalities: for example page 59, line 15, cites sequence without a sequence identifier (SEQ ID NO:). Applicant must submit a new CRF and paper copy of the Sequence Listing, including the sequence on page 59. Applicant must also amend the specification to include the SEQ ID NO: for the sequence. The disclosure is also objected to because page 68, line 25, cites a hyperlink directed to an Internet address. The use of hyperlinks is not permitted under USPTO current policy because the content of such links are subject to a change, resulting in the introduction of New Matter into the specification. Appropriate correction is required.

***Claim Objections***

Claims 1-8 and 12-19 are objected to for reciting non-elected inventions. The claims should be amended accordingly.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 1 and 12-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for failing to recite proper Markush terminology. It is suggested that ---the group consisting of-- be inserted after "from".

Claims 12-19 are indefinite for failing to recite the specific hybridization and wash conditions required for the claimed "high stringency" conditions. Also, ---sequence---, should be inserted before "identity" to clarify that the identity is assessed based on sequence.

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-8 and 12-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated polynucleotide of SEQ ID NO: 35 encoding the fumonisin degrading enzyme of APAO, transgenic plant/plant cell/seed comprising said polynucleotide, does not reasonably provide enablement for any polynucleotide comprising at least 20 contiguous bases of SEQ ID NO: 35, a polynucleotide comprising at least 70%, 80%, and 90% sequence identity to SEQ ID NO: 35 or a polynucleotide that hybridizes thereto under high stringency conditions, complementary polynucleotides, and transformed plants/plant cells/seed comprising said polynucleotide. The specification does not enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to any polynucleotide comprising at least 20 contiguous bases of SEQ ID NO: 35, a polynucleotide comprising at least 70%, 80%, and 90% sequence identity to SEQ ID NO: 35 or a polynucleotide that hybridizes thereto under high stringency conditions having no known function, partially complementary sequences, and a recombinant expression cassette comprising said polynucleotide. The claims are also drawn to transformed plant cell and plants comprising said polynucleotide.

Applicant has provided guidance for the isolated polynucleotide of SEQ ID NO: 35 from *Exophiala spinifera* isolates from maize. *Exophiala spinifera* was recovered from field grown maize kernels. The fungus was found to be capable of growing on fumonisin B1 and B2 (FB1 and Fb2) substrates as sole carbon source. Enzyme active strains of the fungi were used to isolate APAO (Examples 1-3). The isolated polynucleotide of SEQ ID NO: 35 was shown to encode amino polyol amine oxidase (APAO) having fumonisin degrading activity (Example 16). Transgenic maize plants expressing APAO polynucleotide were also disclosed (Example 11)

Applicant has not disclosed or provided sufficient guidance for how to obtain all of the polynucleotides of parts (a)-(c) of claims 1-8 and 12-19. No specific guidance has been provided for any modifications to SEQ ID NO: 35 that resulted in a polynucleotide having at least 70%, 80% and 90% to SEQ ID NO: 35 that encodes a polypeptide having fumonisin degrading activity. Applicant has provided no guidance for a

polynucleotide that hybridizes under high stringency conditions (as broadly defined in the specification) and still encoding APAO. No guidance has been provided for primers specific for APAO, hybridization and wash conditions, which would enable a skilled artisan to obtain only APAO polynucleotides. With respect to a polynucleotide comprising 20 contiguous bases, Applicant has not taught that all polynucleotides comprising 20 contiguous bases of SEQ ID NO: 35 are APAO. For example, Adams et al who teach a sequence comprising 23 contiguous bases of SEQ ID NO: 35 that is unrelated to APAO (see Sequence Search Result, Accession no. AQ280543, pages 1-2). With respect to claims drawn to complementary sequences, the scope of the claims encompasses sequences that are not fully complementary which can be as few as 2 mer. Applicant has not shown that a 2-mer would have any function.

The state of the art teaches that sequence identity does not necessarily imply similar function. For example, Lazar et al (Molecular and Cellular Biology, March 1988, Vol. 8, No. 3, pp. 1247-1257 (U)) teach two proteins that differ only in a single amino acid residue and that do not share the same biological activities (see at least the Title). Broun et al (Science, 13 November 1998, vol. 282, pp. 131-133 (U)) teach that as few as four amino acid substitutions in a protein can change the protein activity (Abstract). The Examiner notes that the nucleic acid sequences encoding the proteins disclosed by either Lazar or Broun would share at least 90% sequence identity and would hybridize to each other under any stringency conditions. Therefore, it is unpredictable if any polynucleotide having 70%, 80% and 90% to SEQ ID NO: 35 and any polynucleotide

that hybridizes thereto under stringent conditions would encode a polypeptide having the APAO activity and specificity.

While one skilled in the art can make polynucleotides having the recited structural characteristics (% of sequence identity or hybridizes under high stringent conditions) routinely, obtaining polynucleotides having said structural characteristics and the functional characteristics of the APAO are considered to require extensive and undue experimentations

In addition, since the only working example disclosed in the specification is limited to unmodified SEQ ID NO: 35, the ability of SEQ ID NO: 35 to encode a polypeptide having fumonisin degrading activity cannot be extrapolated to any variant thereof, absent specific guidance.

Therefore, in view of the broad scope of the claims, the unpredictability in the art in determining function based on sequence homology or hybridizing property, given the limited guidance in the specification, and the limited working examples, the claimed invention is not enabled throughout the scope of the claims.

See *Amgen Inc. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1027 (Fed. Cir. 1991) where the court held that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof. In the instant application, the disclosure of a few polynucleotides of maize APAO, and transgenic plants/plant cells comprising said polynucleotide would not enable claims drawn to any polynucleotide having at least 70%, 80% and 90% to SEQ ID NO: 35 and any polynucleotide that

hybridizes thereto under stringent conditions, partially complementary polynucleotides, and plants/plant cells/seed comprising said polynucleotide.

***Written Description***

Claims 1-8 and 12-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated polynucleotide having at least 70%, 80%, 90% sequence identity to SEQ ID NO: 35, a polynucleotide that hybridizes thereto under high stringency conditions and a polynucleotide comprising at least 20 contiguous bases of SEQ ID NO: 35. The claims are also drawn to a recombinant expression cassette and transgenic plants, plant cells and seed comprising said polynucleotide.

The claimed invention does not meet the current written description requirements for the following reasons. Firstly, the claims do not recite functional language. Secondly, the specification only describes the unmodified polynucleotides of the *Exophiala spinifera* isolates from maize. Thirdly, substantial variation in structures and function are expected among polynucleotides that share 20 contiguous bases. Therefore, the disclosure of SEQ ID NO: 35 does not provide adequate written description for all polynucleotide having at least 70%, 80%, and 90% sequence identity to SEQ ID NO: 35, all polynucleotides that hybridize thereto under high stringency conditions, and all polynucleotides comprising at least 20 contiguous bases of SEQ ID

NO: 35, having no known function. Since Applicant has not described the polynucleotides of the invention, the recombinant expression cassette, transformed plants, plant cells and seed comprising the polynucleotide (claims 14-23) are similarly not described.

Therefore, weighing all the factors above, the written description requirement is not satisfied. See Written description Examination Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices).

See, also *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from the organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. Further, the court stated that to adequately describe a claimed genus, Applicant must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of members of the genus".

### ***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-8 and 12-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,211,434. Although the conflicting claims are not identical, they are not patentably distinct from each other because the invention claimed in both the application and the issued patent encompass SEQ ID NO: 35 and transgenic plants, plant cells and seed comprising SEQ ID NO: 35. The two inventions relate as species/genus. The invention claimed in the application, drawn to an isolated polynucleotide comprising at least 20 contiguous bases of SEQ ID NO: 35, a polynucleotide sequence having at least 70%, 80%, 90% sequence identity to SEQ ID NO: 35 and polynucleotides that hybridize thereto, define the genus; while the invention claimed in the patent, drawn to the isolated polynucleotide of SEQ ID NO: 35, is the species. Since genus is obvious over the species, the invention claimed in the application is obvious over the invention claimed in the patent.

#### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 12-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Duvick et al (5,792, 931).

The claims are drawn to an isolated polynucleotide that hybridizes to SEQ ID NO: 35 under unspecified high stringency hybridization conditions, recombinant expression cassette, vector, and transformed plant, plant cell and seed comprising said polynucleotide. The claims do not recite specific hybridization conditions required for high stringency.

Duvick et al teaches an isolated nucleic acid sequence, from *Exophiala spinifera*, encoding a polypeptide having fumonisin detoxification activity, expression vector, and transformed plant, plant cells and seed expressing said nucleic acid (columns 20, 24-30 and 39-40). The isolated nucleic acid sequence disclosed by Duvick would inherently hybridize to SEQ ID NO: 35 under high stringency conditions, since "high stringency conditions" is open to individual interpretations. Therefore, Duvick discloses all claim limitations.

#### **Remarks**

No claim is allowed.

Papers related to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmission 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday-Thursday from 8:30AM to 5:30PM and every other Friday 9:00AM to 5:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

1/7/03  
Mail



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